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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,957	07/25/2001	Pierre Barbier	20713	7137

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

PESELEV, ELLI

ART UNIT PAPER NUMBER

1623

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

973-235 2363

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Offic Action Summary	Applicati n N .	Applicant(s)
	09/912,957	BARBIER ET AL.
	Examin r Elli Peselev	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the c rrrespondenc address --
Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____ .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-32 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 and 6</u> .	6) <input type="checkbox"/> Other: ____ .

Claims 1-2, 4-18 and 19-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for orlistat, does not reasonably provide enablement for a lipase inhibitor in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification fails to reach or suggest any other lipase inhibitor, except orlistat and it would take an undue amount of experimentation to determine which other lipase inhibitor will be useful in the claimed compositions and methods.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 9 and 16-32 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hug et al (U.S. Patent No. 6,358,522 B1).

Hug et al disclose a pharmaceutical composition which comprises orlistat and polysaccharides, such as methylcellulose (column 2, lines 1-35 and starch (column 5, lines 11-24). Hug et al further disclose the use of said composition for reducing the gastrointestinal side effects associated with orlistat and the treatment of obesity (column 5, lines 52-62). The claimed compositions and methods are anticipated by Hug et al.

In addition, if there are any differences between the claimed composition and method and the prior art composition and method, the differences would appear to be minor in nature and the claimed composition and method, which fall within the scope of the prior art disclosure, would have been *prima facie* obvious to a person having ordinary skill in the art at the time the instant invention was made.

Claims 1-5, 7, 9 and 16-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hadvary et al (U.S. Patent No. 4,598,089), Isler et al (U.S. Patent No. 5,447,953) or Bremer et al (U.S. Patent No. 5,643,874).

Each of Hadvary et al (column 7, lines 15-17) and Bremer et al (column 5, lines 26-28) discloses a composition containing a lipase inhibitor in combination with starch and the use of said composition for treating obesity. Isler et al disclose a composition containing lipase inhibitor in combination with a cellulose derivative (column 2, lines 65-68). The claimed compositions and methods are anticipated therefrom. In addition, if there are any differences between the claimed composition and method and the prior art composition and method the differences would appear to be minor in nature and the claimed composition and method, which fall within the scope of the prior art composition and method, would have been *prima facie* obvious from the said prior art disclosure to a person having ordinary skill in the art at the time the instant invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev
August 7, 2002

Elli Peselev
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800